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Draft Response to Proposal from the Ministry of Social Affairs Regarding Withdrawal of Exemptions from Section 6.1.2 of the Tobacco Act for Catering and Accommodation Establishments and Repeal of the Stipulation on Exemptions from Partitioning into Zones in Canteens.

<u>GENERAL</u>

The Norwegian NMA opposes the proposed amendments to Section 6 of the Tobacco Health Hazards Act - Protection Against Passive Smoking on the grounds that such amendments are unnecessary and lack convincing scientific justification.

The proposed amendment to repeal the exemption for catering and accommodation establishments from the general requirement of Section 6 to provide a smoke - free premise is an impermissible constraint on business owners who are in the best position to judge and respond to the needs of their clients. Similarly, the proposed amendment to require all canteens in the workplace to become smoke-free interferes with the ability of employers to accommodate the needs of all of their employees in a fair and tolerant fashion. Smoking arrangements in these situations should be left to the discretion of hotel and restaurant owners and their guests and to employers and their employees.

The Ministry's proposal is not persuasive as to why any changes are needed to Section 6 as adopted in 1988. The Ministry apparently concedes that there is no evidence that the current provisions addressing smoking in restaurants, hotels and canteens are not satisfactory. Section 6.3, "The factual situation", of the Ministry's proposal admits, "The content of the main rule of Section 6 of the Tobacco Health Hazards Act is such that, if the law functions as intended, one should be able to work, frequent public places and travel without being exposed to tobacco smoke. No surveys have been conducted to show how the stipulations work today as far as 2501049434

infringements are concerned, and there is no overview of cases which have been reported. Communications from the public to the Ministry of Social Affairs and the National Council on Smoking and Health indicate that the Act mainly functions as intended". This suggests there is no real need for change. By the Ministry's own admission, the current provisions of the Act are functioning as intended, and there is no good evidence indicating that problems exist.

Interestingly, Section 6.4 of the Ministry's proposal, "The legal situation in other countries", cites EC Resolution 89/c189/01 in support of further public smoking restrictions. However, EC Resolution 89/c189/01 does not specifically call for a ban on smoking in restaurants, hotels or canteens in the workplace. In fact, the Resolution recognizes "it is appropriate to make provision to permit smoking in part of these establishments and forms of transport" and invites member states to "provide, where necessary, for clearly defined areas to be reserved for smokers". The Resolution does not call for complete and total physical separation of smokers and non-smokers.

The Ministry's proposal clearly bases its suggested amendments to Section 6 on the alleged health effects of so-called "passive smoking" as presented in Section 2.4 of the Ministry's proposal. The Norwegian NMA disagrees with the conclusions of Section 2.4, "Some information on passive smoking", of the proposal which makes numerous general scientific claims about "passive smoking" without citing a single scientific study from Norway. We are of the opinion that the currently available scientific data on environmental tobacco smoke (ETS) do not demonstrate that ETS causes lung cancer, cardiovascular disease or other diseases in non-smokers.

We have provided below comments on some of the specific sections of the Ministry's proposal to amend Section 6.

2.4 "Some Information on Passive Smoking"

The proposal relies on certain underlying scientific assumptions to justify the proposed further smoking restrictions in workplace canteens and catering and accommodation establishments. Neither the very few research reports referred to in the proposal nor any other currently available research data prove that ETS causes disease in non-smokers.

It should be noted that Section 2.4 of the Ministry's proposal makes numerous broad statements concerning the alleged health effects of ETS and vaguely alludes to studies it relies on to justify further public and workplace smoking restrictions. However, the Ministry fails to provide a single scientific citation. This forces us to speculate as to what precise scientific information the Ministry is relying on to support its amendments. Section 2.4 cites no evidence that exposure to ETS in the workplace or in restaurants and hotels has been reported to cause disease in non-smokers.

Due to the lack of scientific citations provided by the Ministry in Section 2.4, we feel compelled to address those scientific studies investigating ETS that must be considered before further public and workplace smoking restrictions can be put forward on public health grounds.

Only a few epidemiological studies have reported a "statistically significant" association between exposure to ETS and certain diseases. Most of these studies have, however, been criticized in the scientific literature on various grounds, for example: failure to take into account confounding factors such as outdoor pollution, occupational exposures to chemicals, age differences, diet and life-style variables, erroneous diagnoses of diseases and use of unreliable questionnaires as initial

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research data. Misclassification of smokers as non-smokers has also created statistical blases.

The argument that ETS exposure increases the risk of lung cancer in non-smokers is largely based on an interpretation of the data from epidemiological studies of nonsmoking women married to smokers. Of the 33 published epidemiological studies on the issue of spousal smoking and lung cancer, none actually measured exposure to ETS; they inferred or "estimated" exposure indirectly by asking questions about contact with smokers. Moreover, more than three-quarters of the studies (27 of the 33) report results that are not statistically significant overall - that is, their conclusions are consistent with the null hypothesis of no association between reported exposure to ETS and lung cancer in non-smokers. The most recent ETS study published, one of the largest studies to date which was funded by the U.S. National Cancer Institute, reported no statistically significant increase in the risk of lung cancer and reported ETS exposure.1

Most significant for potential regulation of workplace canteen smoking, 14 of the epidemiological studies on spousal smoking also assessed reported workplace exposures to ETS by questionnaire. Twelve of the 14 workplace studies report no statistically significant association between ETS and lung cancer in non-smokers. Only two of the studies reported a marginal statistical significance.

Statements in the Ministry's proposal regarding an alleged relationship between heart disease and ETS exposure are presumably based on 12 epidemiological studies that relied on spousal smoking as a measure of ETS exposure. Seven of the 12 studies did not report a statistically significant association and 3 of the 5 that did had very few cases; i.e., they lacked statistical power. In fact, those studies have been widely criticized, 2,3,4

Five epidemiological studies on ETS exposure and heart disease addressed workplace exposure; not one reported a statistically significant association.

Heart diseases are complex, multi-factorial conditions, and the precise pathological mechanisms are unknown. It is unrealistic to try to "blame" a single factor for their cause. There are more than 300 risk factors for these conditions and the extent to which they contribute to any individual's disease is unknown.

Several assessments of ETS exposure and heart disease have been prepared under the auspices of national authorities, including the U.S. National Research Council, the U.S. Surgeon General, the Canadian Health and Welfare Department, the Norwegian Directorate of Health, the Australian Health and Medical Research Council, and the Netherlands Health Council. None concluded that a causal relationship has been demonstrated between exposure to ETS and the development of heart disease.

Clearly, the existing scientific data do not justify further public and workplace smoking restrictions. This is especially so when a number of research reports indicate that non-smokers' exposure to ETS can be effectively minimized by merely separating smokers and non-smokers in the same indoor areas. 5.6.7,8,9

In apparently referencing a draft ETS Risk Assessment Report by the U.S.

Environmental Protection Agency (EPA), the proposal omits to mention that the report was heavily criticized in comments submitted by more than 100 scientists. It is also misleading to refer to statistics from a draft report when the EPA has published its final report in the matter.

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The Ministry's proposal neglects to mention, for instance, that according to the EPA's final report, the risk ratio of lung cancer of non-smokers exposed daily to ETS is 1.19

in relation to a person staying in air free from smoke, not a "30%" increased risk for lung cancer which the Ministry quotes from the earlier EPA draft report. A relative risk of only 1.19, if real, is extremely weak by epidemiological standards.

The Ministry's proposal refers to the conclusion of the EPA Report that classified ETS as a "Group A carcinogen". It is critical to note that the EPA's conclusion has been severely criticized and the EPA has been accused of distorting science to fit its own pre-determined conclusions and to serve its political objective of promoting smoking bans in public places and the workplace.

The EPA largely based its conclusion on a meta-analysis of 11 of the U.S. spousal smoking studies. As originally reported, none of these 11 studies found on overall risk for lung cancer in non-smokers that was statistically significant. If the two most recent U.S. studies are added to the EPA's lung cancer database of 11 studies (the EPA omitted them from its consideration), the overall risk determined would not have been statistically significant. It is also important to note that at this point during the review process, the EPA decided to use 90% confidence intervals to arrive at a statistically significant risk value. Generally accepted scientific convention requires the use of 95% confidence intervals, and if the 95% confidence intervals had been used, the results would not have achieved statistical significance. Clearly, the EPA "engineered" the result it was determined to obtain by lowering the threshold for achieving statistical significance.

The epidemiological studies on spousal smoking relied on by the EPA contained no actual measurement data on exposure to ETS. Instead, responses to questionnaires about possible exposures to ETS were assumed valid and then generalized to estimate the population's exposure to ETS. In addition, the authors failed to consider and adjust for confounding factors commonly related to lung cancer, namely diet, lifestyle, occupation and genetics.

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The EPA also relied on the argument that ETS contains substances similar to those alleged to be carcinogens in mainstream smoke. ETS and mainstream smoke differ significantly in their physical and chemical make-ups. The U.S. National Research Council concluded in its 1986 report on ETS that data on mainstream smoke do not provide a basis for predicting alleged effects of exposure to ETS. Most importantly, the immense quantitative differences between ETS and mainstream smoke would preclude any reliance on mainstream smoke data to draw conclusions about ETS. Scientists have consistently estimated that a non-smoker exposed to ETS is exposed to the range of one to five cigarette equivalents per year. If ETS is considered to be a carcinogen based on the presence of substances found in mainstream smoke, then many commonly encountered products, including drinking water, hamburgers, peanut butter and numerous other products which contain the same substances, should be classified as carcinogens.

To the extent that the Ministry has relied upon the U.S. EPA's Report classifying ETS as a "Group A carcinogen" to support its proposal to further restrict smoking in the workplace and public places, the Ministry should be aware that on June 22, 1993, a group of six tobacco industry organizations filed a lawsuit against the EPA in U.S. federal court challenging the ETS Risk Assessment Report and its conclusions. The main claims are that the EPA used faulty science and improper scientific procedures to arrive at its conclusions, the EPA manipulated the scientific data by selectively reviewing certain studies while intentionally omitting recent studies that contradicted its conclusions and that the EPA used scientific assumptions and methodologies not generally accepted by the scientific community or even by the EPA itself in other risk assessments it had previously conducted. The tobacco industry has asked the court that the EPA ETS Risk Assessment classifying ETS as a "Group A carcinogen" be declared null and void. As the EPA Report faces a serious legal challenge, any reliance on its conclusions to justify stricter smoking regulations seems premature.

6.1 "Current Legislation" - 6.6 "Conclusion"

Section 6.1 of the Ministry's proposal refers to regulations which are effective as of July 1, 1993, requiring smoke - free areas in restaurants, hotels and other catering and accommodation facilities. The regulations will require that at least one-third of the tables, seats and rooms must be smoke - free as well as all common areas that are not serving areas. It is proposed by the Ministry that such requirements be gradually made more stringent eventually culminating in a requirement by July 1, 1997, that all common areas of catering and accommodation establishments be smoke - free except that smoking may be permitted at up to half of the tables and rooms if smoke is not able to penetrate into smoke - free areas. If smoking and smoke - free areas cannot be physically partitioned to ensure that smoke does not penetrate the smoke - free area then the whole locality must be smoke - free.

Exemptions from the general smoke - free requirement can still be applied for; however, the tone of the Ministry's proposal makes it clear that such exemptions will be granted sparingly.

The regulations which became effective July 1, 1993, and which would become much more stringent on July 1, 1997, under the Ministry's proposal impose unreasonable formulae and restrictions on the ability of business owners to satisfy the needs and preferences of their clientele - both smokers and non-smokers. Hotel and restaurant owners are acutely aware of the need to accommodate the needs of their customers and must be given the discretion to find a sensible and profitable way to satisfy all their customers. Government imposed formulae dictating what percentage of tables or rooms must be set aside for smokers and non-smokers are an impermissible interference with such discretion. The hospitality industry knows the needs and preferences of its customers far better than government, and they should be free to choose how best to accommodate their customers' needs.

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The proposed amendments that would go into effect on July 1, 1997, would work a particular hardship on small business owners. It will simply not be feasible, physically or economically, to physically partition certain small establishments to ensure that smoke does not penetrate the smoke - free section. It is of little consolation to the small business owner that a "transition period" is contemplated. The physical layout of certain premises will make partitioning into smoking and smoke - free zones impractical and the expense will be such that many small business owners simply will not be able to afford it either now or in the future. The effect of such a law is to deprive small business owners of the ability to provide for their smoking customers' preferences. The adverse impact of the proposed regulations on the hotel and restaurant businesses is unfair in view of the lack of credible scientific evidence that exposure to ETS in restaurants and hotels would cause disease in non-smokers.

The Ministry's proposal also suggests that the exemption for canteens at the workplace be rescinded to require that smoke may not penetrate into smoke - free zones. This proposal would require the prohibition of smoking at workplace canteens where complete physical separation is not possible. As there is no convincing evidence that exposure to ETS in a workplace canteen would cause disease in nonsmokers, the proposed change to the existing law is completely out of proportion to the perceived "problem".

The proposed amendment is another example of government interfering in a matter that should be resolved between employers and employees in the workplace. Employers recognize different needs among their workforce and must have the freedom to address those needs while maintaining social harmony. Employers and employees are certainly capable of developing a workplace smoking policy to address smoking preferences in canteens without being dictated to by government.

Most workforces consist of smokers and non-smokers. The issue of a policy for smoking in the workplace canteen should be rightfully left to employers and their employees to be resolved in a manner that balances individual worker needs and responsibilities while maintaining a productive and cooperative working environment. Norwegian employers and their employees are perfectly capable of establishing formal or informal policies for smoking in canteens based on mutual tolerance, respect and common courtesy.

Once again, the proposed cancellation of the exemption for workplace canteens from the general requirement of a smoke - free environment would be particularly unfair and burdensome to small businesses. Small businesses with few employees may have neither the space nor the resources to create separate and equal dining facilities in the workplace. Furthermore, any change in the law calculated to produce a smoking ban in certain workplace canteens could have a number of undesired effects such as (1) creating unnecessary tension and lower morale, (2) encouraging people to take extended breaks to leave the work premises to enjoy a cigarette leading to lost productivity, (3) encouraging employees to move to other companies with the resources to provide a partitioned smoking section in the canteen to the detriment of small employers, (4) increasing the risk of covert smoking in unsuitable places, etc.

The optimum solution to the issue of smoking in workplace canteens is to permit employers and employees the freedom to work out a reasonable policy of accommodation that meets the specific needs of the workplace.

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